

FILED

APR 22 2024

Court of Common Pleas
of Lehigh County, PA
Orphans' Court Division

**IN THE COURT OF COMMON PLEAS OF LEHIGH COUNTY, PENNSYLVANIA
ORPHANS' COURT DIVISION**


In re: Power of Attorney of :
GUY D. FERRAIOLO : File No. 2024-OC-0680
Principal :

ORDER

AND NOW, this 22nd day of April, 2024, upon consideration of the *Complaint For Emergency Medical Declaratory Judgment And Emergency Injunctive Relief* filed on April 11, 2024 (“Complaint”) in the Civil Division, and transferred to the Orphans’ Court Division by separate *Order*, and following a trial thereon held April 19, 2024 attended by Plaintiff, Denise Moy, as attorney in fact for Guy Ferraiolo (“Plaintiff”), along with her counsel, Robert N. Rust, III, Esquire, and Ralph C. Loriga, Esquire¹, and by Defendant, St. Luke’s University Health Network and St. Luke’s University Hospital-Bethlehem (collectively “St. Luke’s”), along with their counsel, Mark R. Zolfaghari, Esquire, and upon consideration of the evidence presented, and for the reasons set for the accompanying Memorandum Opinion,

IT IS ORDERED that Plaintiff’s requested declaratory/injunctive relief is DENIED and Judgment is entered in favor of St. Luke’s and against the Plaintiff.

BY THE COURT:


Thomas A. Capehart, A.J.

¹ Ralph C. Loriga is a New York state licensed attorney who was admitted *pro hac vice* to the bar of this Commonwealth by Order dated April 19, 2024 for the limited purpose of seeking injunctive relief.

IN THE COURT OF COMMON PLEAS LEHIGH COUNTY, PENNSYLVANIA
ORPHANS' COURT DIVISION

IN RE: GUY D FERRAILOLO, PRINCIPAL : FILE No. 2024-OC-0680
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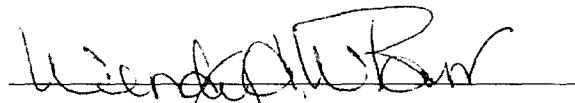
NOTICE OF ENTRY OF ORDER AND MEMORANDUM OPINION

To: <u>NAME</u>	<u>FAX/EMAIL/MAILING ADDRESS</u>
Robert N Rust, III Esq	rrrust@rustlawllc.com
Mark R Zolfaghari, Esq	Mark.Zolfaghari@sluhn.org

Pursuant to Pa. O.C. Rule 4.6(a) you are hereby notified of the entry of *Order And Memorandum Opinion* dated on the date of the time-stamp appearing on the enclosed copy.

Date: April 22, 2024

BY:



Wendy A. W. Parr,

Clerk of Orphans' Court

**IN THE COURT OF COMMON PLEAS OF LEHIGH COUNTY, PENNSYLVANIA
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In re: Power of Attorney of :
GUY D. FERRAIOLO : File No. 2024-OC-0680
Principal :

MEMORANDUM OPINION

Before the court is a request for emergency and permanent mandatory injunctive relief filed by Denise Moy (“Ms. Moy”) on behalf of Guy D. Ferraiolo (“Mr. Ferraiolo”), a critically and terminally ill hospitalized patient presently suffering from stage IV metastatic stomach cancer, seeking to compel Mr. Ferraiolo’s treating physicians at St. Luke’s Hospital in Bethlehem, Pennsylvania¹ (“St. Luke’s”) to administer an unproven experimental regimen of drugs and vitamins (Ivermectin, Mebendazole, Atorvastatin, Itraconazole, Doxycycline, and Disulfiram EGCG, Melatonin, Omega 3 fatty acids, and Vitamin C Vitamin D) (“Experimental Regimen”) with the intention of prolonging Mr. Ferraiolo’s life.

Consistent with its policies, protocols, and applicable standard of care, St. Luke’s refused to administer the Experimental Regimen to treat Mr. Ferraiolo. Plaintiff’s evidence presented at the hearing focused on the alleged safety and efficacy of the Experimental Regimen, however, the uncontradicted evidence established the Experimental Regimen falls outside St. Luke’s standard of care. The court finds that patients do not have a right to treatment that falls outside the health care provider’s standard of care even when a patient is suffering from a terminal condition.

¹ Mr. Ferraiolo is a patient at St. Luke’s University Health Network/St. Luke’s Hospital-Bethlehem Campus.

Regardless of this court's most heart-felt sympathies to Mr. Ferraiolo and his family, we are constrained to deny the requested relief as more fully explained below.

FACTUAL BACKGROUND

In January, 2024, Mr. Ferraiolo, a seventy-one (71) year old retired software engineer, was diagnosed with incurable Stage IV metastatic stomach cancer. He began palliative chemotherapy to prevent the progression of the cancer, but developed tumor lysis syndrome (releasing the cancer contents into the blood) in response to the chemotherapy, causing acute renal failure, requiring dialysis three (3) times per week. Mr. Ferraiolo sought some alternative form of treatment for his condition and sought assistance through his health care proxy,² Dr. Anthony Messina, a retired New York anesthesiologist. In the process, Mr. Ferraiolo found out about an alternate care regimen by Front Line COVID-19 Critical Care Alliance ("FLCCC"), a group conducting an observational cancer study, seeking to treat critical care patients with a combination of repurposed drugs (those approved for one condition but used to treat another), vitamins and supplements described above. ("Case Study"). The Experimental Regimen was suggested to treat Mr. Ferraiolo's metastatic cancer and renal failure and was to be overseen by Dr. Pierre Kory, a Wisconsin licensed critical-care physician.

Mr. Ferraiolo testified remotely from his hospital bed acknowledging his desire and approval to be subject to the Experimental Regimen. He allegedly signed a consent to participate in the Case Study, but the form was never admitted into evidence. Nevertheless, the testimony provided suggests the consent and Case Study, itself, advised that the Experimental Regimen was investigational, not proven or established, and, most significantly not the current standard of care.

² Ms. Moy was a duly authorized Pennsylvania Agent in accordance with the relevant provisions of the Pennsylvania Probate, Estates and Fiduciaries Code, 20 Pa.C.S.A §§5601-5614. The Pennsylvania Power of Attorney nor the Health Care Proxy were not admitted into evidence at the hearing, however, there was no dispute regarding Mr. Ferraiolo's desire to have Ms. Moy and Dr. Messina act on his behalf.

In support of his request to compel St. Luke's to allow this alternative treatment, Plaintiff presented the testimony of Dr. Paul Marik, a non-practicing physician and member of FLCCC, who believed administration of the Experimentally Regimen would be safe, but conceded the Experimental Regimen is not approved by the NCCN (National Comprehensive Cancer Network), a nationally recognized alliance of cancer centers providing guidelines in oncological care. Significantly, Dr. Marik acknowledged that administration of the Experimental Regimen falls outside of, and is not, the current standard of care for treatment of cancer patients, acknowledging there are no guarantees that the Regimen would be effective.

Another of Plaintiff's witnesses, Dr. Erin Grier, a South Dakota physician of internal medicine with a subspecialty in nephrology (the study of kidney disease), testified that she did not believe administration of the Experimental Regimen would be detrimental to Mr. Ferraiolo's ongoing dialysis. Nevertheless, and importantly, she testified that a physician has the right to deny a patient's desired treatment if that requested treatment is not within the accepted standard of care. In other words, the patient does not determine the medical standard of care, the physician does.

St. Luke's presented the testimony of Dr. Melissa Wilson, a physician at St. Luke's board certified in oncology, who after reviewing Dr. Kory's suggested Experimental Regimen, testified the use of repurposed or off label medications is not proper, and should not be used to treat a patient. Dr. Wilson further opined that the proposed treatment of Mr. Ferraiolo is not the recommended standard of care for treatment of gastric cancer.

LEGAL STANDARD

The purpose of a preliminary injunction is to preserve the status quo as it exists or previously existed before the acts complained of, thereby preventing irreparable injury or gross injustice. *Santoro v. Morse*, 781 A.2d 1220, 1229 (Pa. Super. Ct. 2001). Petitioners have the burden

of proving their entitlement to injunctive relief. Warehime v. Warehime, 860 A.2d 41, 47 (Pa. 2004). To meet this burden, Plaintiff must establish each of the following “essential prerequisites”:

First, a party seeking a preliminary injunction must show that an injunction is necessary to prevent immediate and irreparable harm that cannot be adequately compensated by damages. Second, the party must show that greater injury would result from refusing an injunction than from granting it, and, concomitantly, that issuance of an injunction will not substantially harm other interested parties in the proceedings. Third, the party must show that a preliminary injunction will properly restore the parties to their status as it existed immediately prior to the alleged wrongful conduct. Fourth, the party seeking an injunction must show that the activity it seeks to restrain is actionable, that its right to relief is clear, and that the wrong is manifest, or, in other words, must show that it is likely to prevail on the merits. Fifth, the party must show that the injunction it seeks is reasonably suited to abate the offending activity. Sixth and finally, the party seeking an injunction must show that a preliminary injunction will not adversely affect the public interest.”

Summit Towne Centre, Inc. v. Shoe Show of Rocky Mount, Inc., 828 A.2d 995, 1001 (Pa. 2003)

(internal citations omitted). If any one of these essential prerequisites is lacking, Plaintiff fails to meet their burden. Warehime, 860 A.2d at 46.

An injunction that commands the performance of an affirmative act, like in this matter, is considered a “mandatory injunction”, the rarest form of injunctive relief, and is often described as an extreme remedy. Woodward Twp. v. Zerbe, 6 A.3d 651, 658 (Pa. Commw. Ct. 2010). The case for a mandatory injunction must be made by a very strong showing, one stronger than that required for a restraining-type injunction. *Id.* The power to grant or refuse injunctive relief rests in the sound discretion of the court under the circumstances and the facts of the particular case. *Id.* (further citation omitted). In that regard, and like the factors applicable to general injunction relief, a party seeking mandatory injunctive relief must establish the following elements: (1) irreparable harm will occur that is not compensable by money damages; (2) greater injury will result from the denial of the injunction than by granting the injunction; (3) the injunction will restore the status

quo between the parties; and (4) the party seeking relief has a clear right to relief in an actionable claim. *Hatfield Twp. v. Lexon Ins. Co.*, 15 A.3d 547 (Pa. Commw. Ct. 2011).

ANALYSIS

Based upon the evidence presented at the hearing, and weighed by this court, the Plaintiff has not met the heavy burden of proof to establish all elements required for this court to issue a mandatory preliminary injunction.

Accordingly, the issue is not whether the Experimental Regimen constitutes a suitable treatment option for stomach cancer, but rather whether Ms. Moy has identified a clear legal right to the issuance of a mandatory injunction. In that regard, the Superior Court holding in *Shoemaker v. UPMC*, 283 A.3d 885 (Pa. Super. Ct. 2022) is directly on point and controlling. In *Shoemaker*, an agent of a critically ill patient sought to compel a hospital (UPMC) to administer a drug (Ivermectin) to a COVID-19 patient that was not approved by UPMC. The patient's chances of survival were low and UPMC had exhausted its authorized treatment options. The agent/patient offered to sign a release to relieve UPMC and its agents from any liability for use of the unapproved drug. UPMC, however, refused because the treatment was not within UPMC's standard of care. In response thereto, the agent for the patient filed for declaratory and injunctive relief to compel UPMC to provide the patient with the unapproved treatment. The trial court granted the requested relief, resulting in an appeal to the Superior Court by UPMC.

In strongly worded opinion reversing the trial court, the Superior Court agreed with UPMC finding: (1) the activity Plaintiff sought to restrain was not actionable, (2) a right to relief was not clear, (3) the alleged wrong was not manifest, or (4) Plaintiff was not likely to prevail on the merits of their claim. *Id.* at 893-94. As noted by *Shoemaker*, both the agent and her expert admitted the use of Ivermectin to treat COVID-19 patients is outside UPMC's standard of care. *Id.* In the

matter now before this court, and like *Shoemaker*, Ms. Moy's own experts admitted the use of the Experimental Regimen was not the standard of care for cancer patients at St. Luke's in general, nor was it specifically approved by any of Mr. Ferraiolo's treating physicians, or by St. Luke's Hospital's internal policy. As noted by *Shoemaker*, "[t]here is no precedent or applicable law to support the proposition that a patient has a legal right to demand a particular medical treatment against the advice of their treating physicians, to compel a hospital to allow the administration of a medical treatment that contravenes its own hospital policy, or to force a hospital to issue credentials to a physician to administer such a treatment." *Id.* at 894. Indeed, a trial court may not issue an order compelling a hospital to grant credentials to a physician to administer a drug to a patient against the hospital's protocol. *Id.* at 896. A hospital enjoys the discretion to select, train, and supervise physicians who practice on its premises. *Id.*³ This is particularly true in this case because Dr. Kory is not even licensed to practice medicine in Pennsylvania, and accordingly, a duly licensed Pennsylvania physician has not prescribed any of the medications listed in the Experimental Regimen to treat his metastatic cancer. Even more compelling is the fact that other state appellate courts have also declined to compel a healthcare provider to administer a treatment contrary to the provider's professional judgment and outside the standard of care. *Id.* at 896-897.

Next, in reviewing Pennsylvania's applicable health and safety regulations relating to a hospital's obligation to establish a Patient's Bill of Rights (*28 Pa. Code §103.22(b)(5)-(11)*), the *Shoemaker* Court observed that a patient may have the right to full information about his diagnosis, treatment, and prognosis, as well as the right to refuse treatment, but not **the right to demand a**

³ Given the importance of the credentialing process, the Superior Court found the trial court improperly interfered with UPMC's discretion to select, retain, and supervise the physicians who practiced on its premises when it ordered UPMC to allow uncredentialed physicians to administer ivermectin within the UPMC's ICU. Hospitals, not courts, have the resources and authority to determine whether a physician has the appropriate medical training, experience, and personal fitness to be eligible for medical staff privileges, especially within an intensive care unit. The *Shoemaker* Court unequivocally stated that a trial court cannot substitute its judgment for that of a medical provider in the authorization of physicians who practice medicine under their watch.


particular treatment or therapy, especially one against hospital protocol and outside the standard of care, as this language is notably absent from the statute. *Id.* at 895. (emphasis added). Further, federal regulations designed to protect and promote certain rights of patients are not to be construed as a mechanism to demand treatment of services deemed medically unnecessary or inappropriate. *42 C.F.R. 482.13(b)(2)*.

Plaintiff argues that Pennsylvania's Right to Try Act ("RTTA") (35 P.S. §10232.1 *et. seq.*) provides that clear right. We disagree. First, Plaintiff did not plead the RTTA in any manner and thus, it appears improper to now consider it. Moreover, it is unclear if the RTTA provides the patient with any such right as it is unclear whether the RTTA even applies to use of repurposed/off label drugs. And Plaintiff has failed to provide the court with any legal authority for this position. Moreover, the drugs listed in the Experiment Regimen (Ivermectin, Mebendazole, Atorvastatin, Itraconazole, Doxycycline, and Disulfiram) do not appear to meet the definition of "investigational drug, biological product or medical devise" under the RTTA (*35 P.S. 10232.3. Definitions*), Thus, Plaintiff failed to satisfy its necessary burden in this regard.

For all of the foregoing reasons, the court is constrained to deny the request for a mandatory injunction and enters judgment in favor of St. Luke's.

BY THE COURT:

4/27/2024
Date


Thomas A. Capehart, A.J.